K113125

NOV 17 2011

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

The submitter of this premarket notification is:
Theresa Poole Regulatory Affairs Specialist
Patient Monitoring
Philips Medical Systems
3000 Minuteman Road, MS0480
Andover, MA 01810-1099
Tel: 978 659 7621
Fax: 978 685 5624
Email: claire.arakaki@philips.com

This summary was prepared on 10 November 2011.

The name of this device is the IntelliVue MX40 Patient Monitor.
Classification names are as follows:

Classification	ProCode	Description
none	74 MHX	Physiological Monitor, Patient Monitor
§870.1025, II	DSI	Detector and alarm, arrhythmia
§870.1025, II	MLD	Monitor, ST Segment with Alarm
§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
§870.2700, II	DQA	Oximeter
§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
§870.2300, II	MSX	System, Network and Communication, Physiological Monitors
§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency

The modified device is substantially equivalent to the previously cleared MX40 IntelliVue Patient Monitor (K103646). Updated compatibility to lead sets and other devices.

Intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals. Not intended for home use. Intended for use by health care professionals.

The modified device has the same Indications for Use and Intended Use as the legally marketed predicate device.

The modified device has the same technological characteristics as the legally marketed predicate device.

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system

level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that MX40 patient monitor meets all defined reliability requirements and performance claims.

The following voluntary standards were used where applicable for this product modification per FDA Guidance of March 12, 2000 entitled "*Use of Standards in Substantial Equivalence Determinations*":

General Electrical Safety
IEC 60601-1:1998 + A1:1991 + A2:1995

EMC
IEC 60601-1-2:2001 + A1:2004

Safety and Performance
ANSI/AAMI EC 13:2002 Cardiac monitors, heart rate monitors and alarms
ISO EN 9919: 2005
IEC 60601-2-25:1993 + A1:1999
EC 53:1998 + A1:2008 ECG Cables and leadwires
ISO 10993-1:2010 Biocompatability (only applicable to accessory lead wires)
ISO 9919:2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems.
c/o Ms. Theresa Poole
Regulatory Affairs Engineer
Patient Monitoring
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1099

NOV 17 2011

Re: K113125
Trade/Device Name: Philips MX40 Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II (two)
Product Codes: DSI, MHX, MLD, DRW, DQA, DSA, MSX, and DRG
Dated: October 19, 2011
Received: October 24, 2011

Dear Ms. Poole:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113125

Device Name: IntelliVue MX40 Patient Monitor

Indications for Use:

Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals.

Prescription Use Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, ~~Office~~ of Device Evaluation (ODE)

ision Sign-Off)
ision of Cardiovascular Devices

(k) Number K113125